**4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2007-D-0201]**

# Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products--Content and Format; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." This guidance is intended to assist applicants in developing the DOSAGE AND ADMINISTRATION section of labeling. The purpose of this guidance is to assist applicants in ensuring that the DOSAGE AND ADMINISTRATION section contains the dosage- and administration-related information needed for safe and effective use of a drug and that the information is clear, concise, and presented in a manner that is pertinent and understandable to health care practitioners. We are withdrawing the guidance for industry entitled "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products--Content and Format" issued on March 29, 2010, and issuing this draft guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions*: All submissions received must include the Docket No. FDA-2007-D-0201 for "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

*Docket*: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Eric Brodsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6485, Silver Spring, MD 20993-0002, 301-796-0855; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." FDA is also withdrawing its previous guidance for industry, issued on March 23, 2010 (75 FR 13766), which was entitled "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products--Content and Format."

The draft guidance, when finalized, is intended to assist applicants in developing the DOSAGE AND ADMINISTRATION section of labeling to ensure that this section contains the dosage- and administration-related information needed for safe and effective use of a drug and that the information is clear, concise, and presented in a manner that is pertinent and understandable to health care practitioners. Applicants should follow the recommendations in this guidance when developing this section for a new drug submitted to FDA under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or a biologics license application under section 351(a) of the Public Health Service Act, and when revising

existing information in the labeling for a currently approved drug in a supplement to such applications.

This draft guidance provides examples of required and recommended information in the DOSAGE AND ADMINISTRATION section. This guidance provides recommendations on including certain dosage- and administration-related information in the DOSAGE AND ADMINISTRATION section that is particularly critical to the safe and effective use of the drug (e.g., lack of knowledge of the information or nonadherence to a recommendation could have serious consequences for patients).

This draft guidance addresses the dosage and route of administration for each indication in the DOSAGE AND ADMINISTRATION section and information about the dosage range, the starting or loading dose and dosage, titration schedule, the maximum recommended dosage, the maximum recommended duration, monitoring for effectiveness, and concomitant therapy information in the DOSAGE AND ADMINISTRATION section, as appropriate.

This draft guidance also addresses the following information in the DOSAGE AND ADMINISTRATION section:

- Other drugs used before, during, or after drug treatment or administration;
- Dosage modifications for adverse reactions or for drug interactions;
- Dosage in specific populations (e.g., pediatric patients, geriatric patients, patients with renal impairment, patients with hepatic impairment);
- Information about switching to the subject drug from other products or substitution involving the subject drug;
- Recommendations regarding missed dose(s);
- Recommendations in event of vomiting after oral drug administration;
- Recommendations for drug discontinuation or dosage reduction when there are risks of withdrawal; and

- The recommended dosage for fixed-combination drug products and co-packaged products.

Furthermore, this draft guidance addresses when and how to include information in the DOSAGE AND ADMINISTRATION section on the preparation and/or administration of the drug (e.g., parenteral products, a product stored in the refrigerator or freezer, pharmacy bulk packages, imaging bulk packages, solid oral dosage forms with qualified liquids or soft foods, oral dosage forms via enteral feeding tubes, liposome drug products); instructions to avoid harm related to drug handling and administration, radiation dosimetry; and information on drug incompatibilities if the drug is mixed with other drugs. This guidance also provides information on storage instructions for the reconstituted or diluted product.

Finally, this draft guidance describes information that should ordinarily not be included in the DOSAGE AND ADMINISTRATION section.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314 and 21 CFR 601 have been approved under OMB control number 0910-0001 and 0910-0338. The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910-0572.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, or https://www.regulations.gov.

Dated: January 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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